REF

AKIT-ABCR-01

ABCR Antigen Test for Flu A, Flu B, COVID-19 and RSV - Instructions For Use (IFU)

For in vitro diagnostic use only.

Sample Collection Method

Nas

Intended Use

The assaya ABCR Flu, COVID-19, and RSV Antigen Rapid Test is a rapid immunochromatographic assay intended for the qualitative detection of antigens from influenza type A, type B, SARS-CoV-2, and RSV viruses in nasal secretion from symptomatic individuals. This test is intended for in vitro diagnostic use. This test is easy to perform and results can be interpreted in 10 minutes.
Antigens from influenza type A, type B, SARS-CoV-2, and RSV viruses is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results are presumptive, and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out influenza type A, type B, SARS-CoV-2, and RSV virus infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms. The assaya ABCR Flu, COVID-19, and RSV Antigen Rapid Test is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel.

Materials

Each box contains 50 test kits. Each test kit contains:

- 1 SWAC – Sterile Wood Abrasive Collector
- 1 Buffer Tube: Containing Reagent – Sodium Azide(<0.1%); Sodium Hydroxide(<0.5%); Albumin Bovine Serum(<1%)
- 1 Test Indicator

Storage And Disposal

The product should be stored at 15-30℃ , away from direct sunlight. Do not freeze or overheat the test kit or kit reagents. Kit contents are stable until the expiration date printed on the outer box. The indicators must be kept in the foil pouch until use.

Sample Preparation

Before use, check the expiration date of the packaging. If the kit is past its expiration date, do not use. Confirm that all components needed are in the kit.

1.

Obtain the sterile SWAC. Make sure the SWAC head does not touch anything until sample collection.

2.

Insert the SWAC into one nostril and rotate 5 times. Repeat with the other nostril.

Assay Procedure

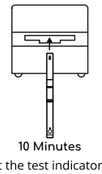
1.

Put the SWAC into the buffer tube. Roll the SWAC 5 times. Leave the SWAC in the buffer tube for 1 minute before inserting the test indicator.

2.

While the SWAC remains in the buffer tube, place the test indicator into the buffer tube with the droplets going down. Leave the test indicator in the buffer tube for 10 minutes. Use the assaya timerDx to keep track of the test time.

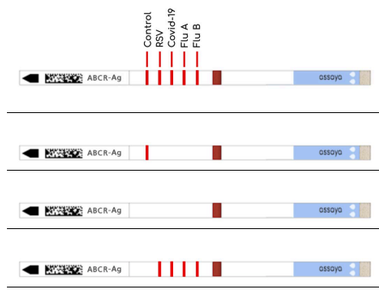
3.



Take out the test indicator and use the result interpretation sticker to read the result at 10 minutes. Do not read the result after 20 minutes. To confirm the result, the test indicator may also be read by the intelligent analyzer eXpress (iaX-2101) after 10 minutes.

Result Interpretation

Positive



Positive Results

At 10 minutes, the appearance of the Control Line and ANY shade of Test Line (Flu A RSV area) on the Test Indicator, indicates a positive result for the presence of Influer CoV-2, and/or RSV viral antigen.
Please refer to the Indicator Line Legend to interpret the test lines.

Negative Results

At 10 minutes, if only Control Line area shows a line, it means a negative result. A ne that the presence of influenza type A, influenza type B, SARS-CoV-2, or RSV viral anti specimen, or the antigen level is below the detection limit.

Invalid Results

If after 10 minutes, the Control Line does not appear, even if any Test Line appears, considered invalid. When invalid, a new test must be performed with a freshly collec sample.

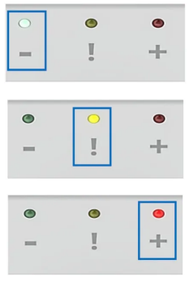
Internal Controls

Two internal procedural controls are needed to confirm correct assay procedure an components. One of two is a line appearing in the "Control Line" area in every run o validity of the test. Another one is a clear background serving as an internal negative background color should be white and not interfere with the reading of the test.

Result Interpretation with the iaX-2101

Please refer to the full iaX-2101 Instructions for Use for complete instructions on ho Place the test indicator into the iaX-2101, with the barcode pointing in.

- A Green (–) indicates a negative result for the presences of Flu A, Flu B, SARS-(antigen or that the antigen level is below the detection limit.
- A Yellow (!) indicates that the test is invalid and a new test must be performec collected specimen sample.
- A Red (+) indicates a positive result for the presences of Flu A, Flu B, SARS-CoV antigen.



GI

Y

Warnings & Precautions

1. For in vitro diagnostic use.
2. Directions should be read and followed carefully.
3. Do not use the kit contents beyond the expiration date printed on the outside of the box.
4. Do not interchange or mix different lots of reagents.
5. Disregard test results beyond specified time (20 min).
6. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
7. Use of Nitrile or Latex gloves is recommended when handling patient samples.
8. Dispose of containers and used contents in accordance with Federal, State and Local requirements.
9. Do not reuse kit components or test devices.
10. The Test Indicator must remain sealed in the protective foil pouch until use.
11. To obtain accurate results, you must follow the Package Insert.
12. Inadequate or inappropriate specimen collection, storage, and transport may yield false test results.
13. Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
14. For optimal test performance, use the nasal Sterile Wood Abrasive Collector (SWAC) supplied in the kit. Using swabs other than provided in the kit may lead to incorrect results.

References

1. Hall CB, Weinberg GA, Iwane MK et al. The burden of respiratory syncytial virus children. N. Engl. J. Med.360(6),588–598 (2009).
2. Nair H, Nokes DJ, Gessner BD et al. Global burden of acute lower respiratory in respiratory syncytial virus in young children: a systematic review and meta-ana Lancet375(9725),1545–1555 (2010).
3. Englund. J.A., P. A. Peidra, A. Jewell, K. Patel, B. B. Baxter and E. Whimbey. 1996. Rapid diagnosis of respiratory syncytial virus infections in imm adults. J. Clin. Microbiol. 34:1649-1653.
4. Crowcroft, N.S., F. Cutts and M.C. Zambon. 1999. Respiratory syncytial virus: ar cause of respiratory infection, with prospects for a vaccine. Commun Dis Publi
5. Barenfanger, J., C. Drake, N. Leon, T. Mueller and T. Troutt. 2000. Clinical and fi rapid detection of respiratory viruses: an outcomes study. J. Clin. Microbiol. 38:
6. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition. U.S. Dep Human Services, CDC, NIH, Washington, DC (2007).
7. Christopher King and Fred M. Henretig, Textbook of Pediatric Emergency Proce 1125-1146, Obtaining Biologic Specimens. (1997).

Product Limitations

1. The contents of this kit are to be used for the qualitative detection of Flu A, Flu B, SARS-CoV-2, & RSV antigen by nasal SWAC. For quantitative detection of the assay, use the iaX-2101. Please refer to the iaX-2101 IFU for full instructions on using the iaX-2101.
2. Positive test results do not rule out co-infections with other pathogens.
3. Negative test result do not rule out influenza type A, type B, SARS-CoV-2, or RSV viral infections. Negative results should be confirmed by molecular test.
4. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
5. Failure to follow the test procedure and interpretations of test results may adversely affect test performance and/or invalidate the test results.
6. Test results must be evaluated in conjunction with other clinical data available to the physician.
7. Antibodies may fail to detect, or detect with less sensitivity, when influenza type A, type B, SARS-CoV-2, or RSV viruses that have undergone minor amino acid changes in the target epitope region.

Limit of Detection (LoD)

The limit of detection (LoD) for the assaya ABCR Flu, COVID-19, and RSV Antigen Rapid Test was established in an analytical sensitivity study performed in clinical nasal matrix. The LoD concentrations identified for each strain tested are listed in the table below.

	Viruses	Strain	LoD
1	Flu A	A/TW/1121/2017 (H1N1)	6.96x10^1 TCID50/mL
2	Flu B	B/TW/2872/17 (Vic)	1.28x10^1 TCID50/mL
3	SARS-CoV-2	gamma-inactivated SARS-CoV-2 (USA- WA1/2020), NR-52287)	2.8x10^1 TCID50/mL
4	RSV	A2 (ATCC VR-1540)	2.24x10^1 TCID50/mL
5	RSV	18537 (ATCC VR-1580)	8.89x10^1 TCID50/mL

Interference

Nasal spray products, hemoglobin, and common chemicals were evaluated and did not interfere with the assaya ABCR Flu, COVID-19, and RSV Antigen Rapid Test in clinical nasal matrix at the levels tested below.

	Interference Substances	Testing Conc.		Interference Substances	Testing Conc.
1	Afrin (Oxymetazoline)	15%v/v	15	Mupirocin	10mg/ml
2	Aspirin	20mg/ml	16	Nasal Ointment	10%
3	Chloraseptic(Menthol/Benzocaine)	1.5mg/ml	17	Nasal Washing Salt	20mg/ml
4	CVS Nasal Drops (Phenylephrine)	15%v/v	18	NASONEX Aqueous Nasal Spray	10%
5	CVS Saline Nasal Spray	15%v/v	19	Oxymetazoline HCl	10mg/ml
6	Dextromethorphan	10mg/ml	20	Phenylephrine HCl	100mg/ml
7	Diphenhydramine HCl	5mg/ml	21	Ponstan	20mg/ml
8	Fisherman's Friend	1.5mg/ml	22	Ricola (Menthol)	1.5mg/ml
9	Fluticasone Propionate	5% v/v	23	Sore Throat Phenol Spray	15%v/v
10	Hemoglobin	20mg/ml	24	Sterimin Nasal Spray	10%
11	Homeopathic (Alkaloi)	1:10 dilution	25	Tamiflu (Oseltamivir Phosphate)	5mg/ml
12	Hosoon Troches (ROOT)	20mg/ml	26	Tobramycin	4ug/ml
13	Ibuprofen	20mg/ml	27	Whole Blood	4%
14	Mucin	0.5%	28	Zicam	5%v/v

Cross Reactivity

The cross-reactivity of the assaya ABCR Flu, COVID-19, and RSV Antigen Rapid Test was performed on the positive and negative clinical matrix containing high levels of non-target microorganisms. Bacteria was tested at a target concentration between 106 and 1010 cfu/mL and viruses were tested at concentrations between 105 and 108 TCID50/mL (or pfu/mL). No cross-reactivity or interference was seen when tested at the potentially interfering concentrations. The bacteria and viruses tested were listed in the table below.

Bacterial Panel					
1	*Bordetella pertussis*	9	*Staphylococcus epidermidis*	17	*Streptococcus sanguis*
2	*Candida albicans*	10	*Streptococcus pneumoniae*	18	*Salmonella enteritidis*
3	*Chlamydia pneumoniae*	11	*Streptococcus pyogenes*	19	*Streptococcus Group A*
4	*Escherichia coli*	12	*Legionella pneumophila*	20	*Streptococcus Group B*
5	*Haemophilus influenzae*	13	*Salmonella typhi*	21	*Streptococcus Group C*
6	*Mycoplasma pneumoniae*	14	*Vibrio cholerae*	22	*Streptococcus Group F*
7	*Pseudomonas aeruginosa*	15	*Serratia marcescens*	23	*Streptococcus Group G*
8	*Staphylococcus aureus*	16	*Streptococcus mutans*		
Viral Panel					
1	Adenovirustype7	7	Enterovirus (EV71)	13	Rhinovirus (HRV14)
2	Adenovirustype41	8	Human Parainfluenza Virus (HPIV) Type I*	14	MERS-CoV
3	Human Metapneumovirus(hMPV3type B1)	9	Human Parainfluenza Virus (HPIV) Type II*	15	Human Parainfluenza Virus (HPIV) Type IV
4	HumancoronavirusZ29E*	10	Human Parainfluenza Virus (HPIV) Type III*	16	HumancoronavirusNL63
5	HumancoronavirusOC43*	11	Human Parainfluenza Virus (HPIV) Type IV	17	Echovirus type 11
6	EnterovirusType68	12	Respiratory syncytial virus (Subgroup B)*	18	Herpes simplex virus type2

Technical Support

Email: support@assaya.com (mailto:support@assaya.com)

Adverse Events Reporting

Use this link to report any adverse events: assaya.com/ae (https://assaya.com/ae)

Ordering Information

Catalog Number (REF): AKIT-ABCR-01
50 pcs per box (Carton of 50 test kits)

Symbol Legend

REF Catalog Number	Consult Package Insert	Do
LOT Batch Code	Manufacturer	Contains su
IVD In Vitro Diagnostic Medical Device	Temperature Limit	Do not use if and cons

Manufacturers

IVD

Panion & BF Biotech Inc. Xizhi Factory
8F, No.308-8, Sec. 1, Datong Rd., Xizhi Dist.,
New Taipei City 22146 Taiwan
Web: vstriptech.com/ (http://www.vstriptech.com/)

Nasal SWAC

Taiwan Swabs Technology Company Inc.
No.329-1, Sucuo, Anding Dist.,
Tainan City 745, Taiwan
Web: yt-swabs.com.tw/eng (http://www.yt-swabs.com.tw/eng)

Distributor

Apollo BioTech Co. Ltd.
18F-1 No. 75 Xintai 5th Road
Xizhi 22101
New Taipei City, 22101
TAIWAN
Web: apollo.bio/ (https://apollo.bio/)

Assaya Pvt. Ltd. Singapore
160 Robinson Road,
#14-04 Singapore Business
Federation Centre
Singapore 068914
Web: assaya.com/ (https://assaya.com/)